

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD,
INC., POLYPROPYLENE HERNIA
MESH PRODUCTS LIABILITY
LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
Stinson v. Davol, Inc., et al.,
Case No. 2:18-cv-01022

MOTIONS IN LIMINE OPINION & ORDER NO. 50

Defendants' Motion *in Limine* ("MIL") No. 7

Defendants C.R. Bard, Inc. and Davol, Inc. filed a Motion *in Limine* to Exclude Evidence or Argument Concerning the 2011 Puerto Rico Line Fire (Defendants' MIL No. 7, ECF No. 239), which is opposed by Plaintiff Aaron Stinson (ECF No. 249). For the reasons that follow, the Court **GRANTS** Defendants' MIL No. 7.

I. Background¹

Plaintiff's case will be tried as the third bellwether selected from thousands of cases in this multidistrict litigation ("MDL") titled *In Re: Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Products Liability Litigation*, 2:18-md-2846. The Judicial Panel on Multidistrict Litigation described the cases in this MDL as "shar[ing] common factual questions arising out of allegations that defects in defendants' polypropylene hernia mesh products can lead to complications when

¹ For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order in this case. (Dispositive Motions Order ("DMO") No. 7, ECF No. 225.) All docket citations are to the *Stinson* case, 2:18-cv-1022, unless otherwise noted.

implanted in patients, including adhesions, damage to organs, inflammatory and allergic responses, foreign body rejection, migration of the mesh, and infections.” (Case No. 2:18-md-02846, ECF No. 1 at PageID #1–2.)

Plaintiff brings this action to recover for injuries sustained as a result of the implantation of an Extra-Large PerFix Plug hernia mesh device, alleging that Defendants knew of the risks presented by the device but marketed and sold it despite these risks and without appropriate warnings. After summary judgment, the following claims remain for trial: design defect, failure to warn, negligence, breach of express warranty, and breach of implied warranty; the Court has reserved judgment on Plaintiff’s claims for manufacturing defect, certain damages, and claims related to his current Bard Mesh implant.

The relevant facts here are that in 2015 Plaintiff underwent a right inguinal hernia repair with an Extra-Large PerFix Plug mesh, a product manufactured by Defendants. In 2017, Plaintiff underwent exploratory surgery to determine if he had a recurrent hernia or nerve entrapment because of chronic pain in his right groin area. The explanting surgeon, Dr. Radke, noted extensive scarring and found “a large ball approximately 2.5 cm in diameter of rolled up mesh next to the pubic tubercle.” (ECF No. 89-22 at PageID #1134.) Dr. Radke removed the mesh, which he described as “slow going and extremely difficult” because of the significant scarring. (*Id.*) Dr. Radke then repaired the hernia with another of Defendants’ products, Bard Marlex Mesh. (*Id.*) Even after the explant surgery, Plaintiff claims to have continuing chronic pain and other complications.

II. Standards

“Neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure explicitly authorize a court to rule on an evidentiary motion *in limine*.” *In re E.I. du Pont de Nemours & Co.*

C-8 Pers. Injury Litig., 348 F. Supp. 3d 698, 721 (S.D. Ohio 2016). The practice of ruling on such motions “has developed pursuant to the district court’s inherent authority to manage the course of trials.” *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). “The purpose of a motion *in limine* is to allow a court to rule on issues pertaining to evidence prior to trial to avoid delay and ensure an evenhanded and expedient trial.” *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (citing *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004)). However, courts are generally reluctant to grant broad exclusions of evidence before trial because “a court is almost always better situated during the actual trial to assess the value and utility of evidence.” *Koch v. Koch Indus., Inc.*, 2 F. Supp. 2d 1385, 1388 (D. Kan. 1998); accord *Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975). Unless a party proves that the evidence is clearly inadmissible on all potential grounds—a demanding requirement—“evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context.” *Ind. Ins. Co.*, 326 F. Supp. 2d at 846; see also *Koch*, 2 F. Supp. 2d at 1388 (“[A] court is almost always better situated during the actual trial to assess the value and utility of evidence.”). The denial, in whole or in part, of a motion *in limine* does not give a party license to admit all evidence contemplated by the motion; it simply means that the Court cannot adjudicate the motion outside of the trial context. *Ind. Ins. Co.*, 326 F. Supp. 2d at 846.

Relevant evidence is “evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.” Fed. R. Evid. 401. “Irrelevant evidence is” inadmissible. Fed. R. Evid. 402. A court may exclude relevant evidence under Federal Rule of Evidence 403 “if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.”

Fed. R. Evid. 403. Rule 404(a) prohibits character or propensity evidence, “[e]vidence of a person’s character or character trait” used “to prove that on a particular occasion the person acted in accordance with the character or trait.” Fed. R. Evid. 404(a). Rule 404(b) prohibits evidence of other acts “to show that on a particular occasion the person acted in accordance with the character.” Fed. R. Evid. 404(b)(1). In other words, the Federal Rules of Evidence do not permit parties to introduce evidence that tempts a jury to conclude that because a party acted badly before, he must have acted badly this time as well. *Old Chief v. United States*, 519 U.S. 172, 180–82, 117 S.Ct. 644, 136 L.Ed.2d 574 (1997). Evidentiary rulings are made subject to the district court’s sound discretion. *Frye v. CSX Trans., Inc.*, 933 F.3d 591, 598 (6th Cir. 2019); *see also Paschal v. Flagstar Bank*, 295 F.3d 565, 576 (6th Cir. 2002) (“In reviewing the trial court’s decision for an abuse of discretion, the appellate court must view the evidence in the light most favorable to its proponent, giving the evidence its maximum reasonable probative force and its minimum reasonable prejudicial value.”).

III. Analysis

Defendants seek to exclude evidence concerning a 2011 line fire at their Puerto Rico manufacturing facility.² (ECF No. 239.) According to Defendants, evidence of the fire is irrelevant to Plaintiff’s claims and unfairly prejudicial to Defendants. Defendants’ answers to Plaintiff’s interrogatories regarding the line fire “affirm that the materials used in Plaintiff’s device were stored in an entirely different location at the time of the line fire, and that all exposed materials were discarded in accordance with standard procedures.” (*Id.* at PageID #9329.) Therefore, “[w]ithout any evidence that the 2011 line fire affected Plaintiff’s particular device, let alone that

² For a more detailed factual background regarding the line fire, see the Court’s Discovery Order at ECF No. 236.

it contributed to his injuries, any evidence or argument about the line fire would not be probative of any issue in the case.” (*Id.* at PageID #9329–30.) Defendants also point to the fact that none of Plaintiff’s timely-designated experts has offered an opinion that the line fire or any other manufacturing defect caused or contributed to Plaintiff’s injuries. (*Id.* at PageID #9332–33.)

Plaintiff responds that evidence of the line fire and the quality controls in place is relevant to his claims. According to Plaintiff, Defendants’ handling of the line fire and quality management systems (“QMS”) in place are “relevant to whether Defendants knew or should have known that the PerFix [Plug] was unreasonably dangerous for Plaintiff’s strict liability design defect claim, and whether Defendants’ conduct was reasonable and Plaintiff’s harm foreseeable as a result of Defendants’ long-standing faulty quality systems.” (ECF No. 249 at PageID #9521.) He also argues that a single expert need not supply every link in the chain of the theory of the case, and his “numerous experts” show the link between Defendants’ behavior and his injuries. (*Id.*) Plaintiff points to Dr. Babensee’s opinions about the lack of biocompatibility, Dr. El-Ghannam’s opinions regarding polypropylene and the PerFix Plug, and Dr. Grischkan’s opinions describing the PerFix Plug’s defects. (*Id.* at PageID #9522.)³ Evidence regarding the line fire “shows systemic failures within the company” which “affect all Bard hernia mesh products, including the PerFix [Plug].” (*Id.*) Plaintiff also argued that there is nothing unfairly prejudicial or confusing about evidence related to the line fire or “Defendants’ maintenance and handling of the materials used in the PerFix Plug implanted in [Plaintiff], especially since Defendants claim that it is clear from the evidence

³ Plaintiff points to Dr. Michael Beatrice’s opinions regarding the line fire and related QMS issues. (ECF No. 249 at PageID #9521.) Dr. Beatrice was added as a proposed expert during the ongoing discovery regarding the line fire and is currently the subject of a pending motion to strike (*see* ECF No. 218).

produced to date” shows that any material exposed to the line fire was disposed of and not used in Plaintiff’s device. (*Id.* at PageID #9523.)

Plaintiff also disputes that evidence of the line fire would be impermissible character evidence, arguing that it would fit into the exceptions enumerated in Rule 404(b)(2), which provides that evidence of other crimes, wrongs, or acts when used to show “motive, opportunity, intent, preparation, plan, knowledge, identity, absence of mistake, or lack of accident.” Fed. R. Evid. 404(b)(2). He points to the Court’s prior rulings, including a ruling regarding FDA investigations and third-party audits, which the Court permitted in a previous bellwether case, only if the plaintiff could show Defendants committed the same or substantially similar violations in relation to the Ventralight ST prior to implantation in that plaintiff. (Case No. 18-cv-1509, MIL Order No. 5, ECF No. 359 at PageID #18791.) However, Plaintiff here does not show that “Defendants committed the same or substantially similar violations” in relation to the manufacture of Plaintiff’s PerFix Plug. Instead, he argues that the line fire shows systemic “significant issues” with Defendants’ QMS, and the issues may have also been present when Plaintiff’s device was manufactured four years later.

As Defendants point out, this Court has repeatedly held that a plaintiff may not introduce evidence unrelated to the plaintiff’s claim solely to demonstrate a “pattern of conduct,” which is propensity reasoning prohibited by Federal Rule of Evidence 404(a). (Case No. 18-cv-1509, MIL Order No. 11, ECF No. 415 at PageID #22188; Case No. 18-cv-1320, MIL Order No. 36, ECF No. 312 at PageID #17408; Evidentiary Motions Order No. 27, ECF No. 237 at PageID #9325–26.) Plaintiff may not use evidence of the 2011 line fire to show that Defendants’ QMS systems were deficient at the time of the fire, and therefore must have been deficient when Plaintiff’s device was manufactured. Additionally, as the Court has more fully explained in its previous Discovery

Orders (ECF Nos. 236, 266), evidence of the 2011 line fire is not relevant to the manufacture of Plaintiff's device over four years later. Defendants produced a signed Inventory Disposal Authorization and produced verified answers to interrogatories confirming that all materials affected by the line fire were disposed of and not used in the manufacturing of any device, including Plaintiff's.

IV. Conclusion

For the reasons set forth above, the Court **GRANTS** Defendants' MIL No. 7 (ECF No. 239).

As with all *in limine* decisions, this ruling is subject to modification should the facts or circumstances at trial differ from that which has been presented in the pre-trial motion and memoranda.

IT IS SO ORDERED.

6/12/2023
DATE

s/Edmund A. Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE